

PATENT COOPERATION TREATY

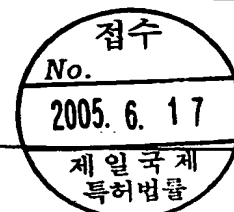
PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY



(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference PCA40631-TGI	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/KR2004/001385	International filing date(day/month/year) 10 JUNE 2004 (10.06.2004)	Priority date (day/month/year) 10 JUNE 2003 (10.06.2003)
International Patent Classification (IPC) or national classification and IPC IPC7 C12Q 1/00		
Applicant TOOLGEN, INC. et al		



<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____ containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand 07 APRIL 2005 (07.04.2005)	Date of completion of this report 15 JUNE 2005 (15.06.2005)
Name and mailing address of the IPEA/KR  Korean Intellectual Property Office 920 Dunsan-dong, Seo-gu, Daejeon 302-701, Republic of Korea Facsimile No. 82-42-472-7140	Authorized officer LEE, CHUNG HO Telephone No. 82-42-481-8160 

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4)
- ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☒ the international application as originally filed/furnished
- ☐ the description:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the claims:
- pages _____ as originally filed/furnished
- pages* _____ as amended (together with any statement) under Article 19
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the drawings:
- pages _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☐ the sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/KR2004/001385

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**I. Statement**

Novelty (N)

Claims 1-81

YES

Claims None

NO

Inventive step (IS)

Claims 1-81

YES

Claims None

NO

Industrial applicability (IA)

Claims 1-81

YES

Claims None

NO

2. Citations and explanations (Rule 70.7)

Reference is made to the following document:

D1: J. Biol. Chem., vol. 272, no. 14, pp. 9573-9580 (1997)

I. Novelty and Inventive Step

Claims 1-38 of the present invention relate to a chimeric protein comprising: a plurality of zinc finger domains and a heterologous protein transduction domain, wherein the chimeric protein specifically binds to a site in a gene and can regulate transcription of the gene in a cell.

Claim 39 of the present invention relates to a nucleic acid comprising a coding sequence that encodes a polypeptide that comprises a zinc finger domain and a heterologous protein transduction domain.

Claims 40-52, 57-78, 80, 81 of the present invention relate to a method of gene expression in a cell of a subject with chimeric DNA binding protein.

Claims 53-56 of the present invention relate to a transducible DNA binding poly peptide.

Claim 79 of the present invention relates to a host cell that comprises a nucleic acid comprising a coding sequence and promoter operably linked to the coding sequence.

D1, which has been published before the priority date of the present invention, discloses a chimeric protein between core promoter-binding protein (CPBP, having three zinc fingers) and Gal4 DNA binding domain increased in the activity of an heterologous reporter gene containing Gal4 DNA binding sites.

(Continued on Supplemental Sheet.)

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Box No. V

Compared with the present invention, the above-mentioned prior art document does not disclose the chimeric protein comprising a heterologous protein transduction domain, effective for translocating the protein across a cellular membrane. Thus claims 1-81 are novel under PCT Article 33(2).

In addition, the chimeric protein comprising: a plurality of zinc finger domains and a heterologous protein transduction domain, which specifically binds to a site in a gene and can regulate transcription of the gene in a cell, and the method of altering gene expression of the same chimeric protein in claims 1-81 are not considered to be easily invented by a person skilled in the art with the teaching of the prior art.

Therefore, the subject matter of claims 1-81 of the present invention complies with the requirements of novelty and inventive step under PCT Article 33(2) and (3).

II. Industrial Applicability

There is no reason for forming a negative opinion about the industrial applicability of this application. Consequently, claims 1-81 appear to meet the requirement of PCT Article 33(4).